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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/314,540	05/19/1999	ROBERT S. LANGER	0492611-0335	5363

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 07/09/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/314,540

Applicant(s)

LANGER ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-13,65-68,73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-11,13,66-68,73 and 74 is/are rejected.
- 7) ☒ Claim(s) 12 and 65 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

Amino acid sequences which are subject to the sequence disclosure rules are present, e.g., at page 9, lines 23, 24, and 26; page 15, lines 17, 19, 23, 25, and 27; page 16, lines 3 and 9; and page 19, line 9; of the specification. However, no sequence listing has been submitted. Further, SEQ ID NOS must be inserted after every amino acid sequence subject to the sequence disclosure rules. See 37 CFR 1.821(d).

Applicant must provide an original computer readable form (CRF) copy of the Sequence Listing, an original paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b).

2. Applicant is advised that should claim 2 be found allowable, claims 7 and 8 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 7 and 8 are identical in scope with claim 2 as amended in Applicants' latest response. It is recommended that Applicants cancel or amend these claims in the response to this Office action.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 6-11, 13, 66, 73, and 74 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-52 of copending Application No. 09/600,502. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '502 application anticipate the instant claims. In particular, the '502 application claims (see especially claims 1, 3, 6, and 11) the ligand-biotin-avidin or streptavidin-biotin-PLA-PEG structure required by the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 2, 6-8, 10, 11, 13, 66, 73, and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyce (U.S. Patent No. 5,273,900). Boyce teaches biotinylated collagen (which corresponds to Applicants' anchor attached to or incorporated into a biodegradable polymer) to which is attached a biotinylated biologically active molecule (which corresponds to Applicants' tag attached to a ligand) through avidin (which corresponds to Applicants' adapter). The

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collagen is combined with a mucopolysaccharide in the form of membranes, which can be laminated and crosslinked. The biologically active molecule can be various growth factors, hormones, antibiotic, or anti-inflammatory compounds (which correspond to Applicants' therapeutic agent). See, e.g., Figure 12E; column 7, lines 7-62; and column 10, lines 6-44.

Collagen is a polyamide and a polyprotein.

6. Claims 1, 2, 6-8, 10, 11, 13, 66-68, 73, and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al (U.S. Patent No. 5,512,294). Li et al teach nanoscale polymerized liposome particles to which is attached metal chelators and imaging enhancement agents, and also to which is attached biotin groups for binding of biotinylated antibodies through avidin or streptavidin. Polymers such as polyethylene glycol, polypropylene glycol, and polyglycine (which is a polyamide) can be present as part of the polymerized liposomes. See, e.g., the Abstract; Figure 16; column 2, lines 58-66; column 4, lines 8-9; column 10, lines 4-23; and claim 1. The polymerized liposomes correspond to Applicants' biodegradable polymer; the biotin groups attached to the polymerized liposomes correspond to Applicants' anchor; the avidin or streptavidin correspond to Applicants' adapter; and the biotinylated antibodies correspond to Applicants' tag-ligand.

7. Applicant's arguments filed June 11, 2003 have been fully considered but they are not persuasive.

Applicants did not respond to the sequence listing requirement set forth in the previous Office action and repeated in paragraph 1 above. Because of the length of time it takes for STIC to review a sequence listing submission, and because of the possibility of error in any sequence listing, it is recommended that Applicants submit a sequence listing as soon as possible.

The declarations under 37 CFR 1.132 filed June 11, 2003 are sufficient to show that the Patel et al article (FASEB J., Vol. 12, pages 1447-1454) and the Cannizzaro et al article (Biotechnol. Bioeng., Vol. 58, pages 529-535) are not by another and are therefore not prior art under 35 U.S.C. 102(a). Accordingly, the rejections set forth in paragraphs 9 and 10 of the previous Office action are overcome.

The anticipation rejection based upon Boyce (U.S. Patent No. 5,273,900) is maintained. Applicants contend that Boyce does not teach an anchor moiety which incorporated into the polymer prior to formation of the biomaterial architecture, as opposed to being attached to the surface of the polymer after the formation of the biomaterial architecture. However, column 10, lines 37-40, teaches that it is the solubilized collagen that is biotinylated, i.e. the collagen/polymer is modified with the biotin/anchor prior to formation of the dermal membrane/biomaterial architecture. Example IV of Boyce show biotinylation of solubilized collagen before the collagen is spotted onto nitrocellulose paper, i.e. before the formation of the biomaterial architecture. Accordingly, Boyce meets Applicants' claim requirement. It is also noted that independent claim 1 does not require the presence of a "biomaterial architecture", and that Applicants' arguments therefore do not directly pertain to the rejection of this claim.

The anticipation rejection based upon Li et al (U.S. Patent No. 5,512,294) is maintained for reasons analogous to those set forth above with respect to Boyce. Li et al teach biotinylation of the lipids prior to formation of the polymerized lipids, i.e. prior to formation of the biomaterial architecture. See, e.g., Figure 11 and column 9, lines 9-21. Figure 16 clearly shows the anchor moiety incorporated into the polymerized liposome. Applicants argue that in Li et al, "the biotinylated antibody-avidin conjugate is not incorporated into the polymer during

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polymerization, but is attached to the polymer in a post-processing step.” The examiner agrees. However, this is exactly what is disclosed in Applicants’ specification (see, e.g., page 3, lines 9-12, and Examples 1 and 4) and thus does not distinguish over Li et al. Further, to the extent that there may be a difference in synthesis between Li et al and Applicants’ claimed product, it should be noted that Applicants are claiming a product, not a method of synthesis or even a product-by-process. Patentability must be based upon claimed, not unclaimed, differences over the prior art.

8. Claims 12 and 65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

July 9, 2003